Court File No. CV-23-00000114-0000

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

DANIEL HARTMAN

Plaintiff

and

PFIZER CANADA ULC, PFIZER INC. and
BIONTECH MANUFACTURING GMBH

Defendants

STATEMENT OF DEFENCE OF BIONTECH MANUFACTURING GMBH

1. The defendant, BioNTech Manufacturing GmbH ("**BioNTech**") admits the allegations contained in paragraphs 9, 34, 70 of the Fresh as Amended Statement of Claim.

2. Unless expressly admitted herein, BioNTech denies each and every remaining allegation of fact, and all claims for relief, contained in the Fresh as Amended Statement of Claim. BioNTech specifically denies that the plaintiff is entitled to the relief sought in paragraph 1 of the Fresh as Amended Statement of Claim.

A. THE DEFENDANTS

3. BioNTech is a German biotechnology company headquartered in Mainz, Germany, involved in the manufacture of mRNA-based pharmaceutical products to combat infectious and life-threatening diseases. At all relevant times, BioNTech was the market authorization holder

for the Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) (the "**Pfizer-BioNTech COVID-19 Vaccine**") in Canada.

4. Pfizer Canada ULC (together with Pfizer Inc., "**Pfizer**") was responsible for importing and distributing the Pfizer-BioNTech COVID-19 Vaccine in Canada. Among other things, Pfizer performed pharmacovigilance activity and post-authorization reporting to Health Canada.

B. BACKGROUND

i. The COVID-19 Pandemic

5. In 2020, coronavirus disease ("**COVID-19**"), caused by the novel severe acute respiratory syndrome coronavirus 2, spread around the world. COVID-19 outcomes range from asymptomatic to deadly and can include ongoing health problems lasting for months or years in the form of "long COVID" or "post-COVID-19 condition".

6. By March 11, 2020, COVID-19 had spread to 114 countries worldwide and the World Health Organization declared the COVID-19 outbreak a global pandemic, with Canada following suit and Ontario, specifically, declaring a state of emergency on March 17, 2020.

7. Since the outset of the pandemic, there have been approximately 778 million reported cases of COVID-19 worldwide, and more than 7 million reported COVID-19 related deaths.

8. In Canada, there have been almost 5 million reported cases of COVID-19 and more than 60,000 reported COVID-19 related deaths.

ii. Overview of the Response to the COVID-19 Pandemic

9. In response to the COVID-19 pandemic and given the need for COVID-19 diagnosis, treatment, mitigation, and prevention options:

(a) Health Canada introduced COVID-19 related interim orders in 2020 and 2021 as permitted under subsection 30.1(1) of the *Food and Drugs Act* RSC 1985, c F-27 (the "*FDA*"); and

(b) Pfizer Inc. and BioNTech SE, an affiliate of BioNTech, agreed to engage in research and development in respect, among other things, potential pharmaceutical and vaccine products, including in response to the COVID-19 pandemic; and

(c) the Pfizer-BioNTech COVID-19 Vaccine was developed to combat the pandemic; it has been shown to be effective at preventing COVID-19, it also reduces the risk of severe COVID-19 complications, such as death, and it can also decrease the risk of long COVID-19 (health problems persisting or developing after an initial COVID-19 infection).

iii. The Product Development and Regulatory Approval Process

10. On March 17, 2020, Pfizer and BioNTech announced a strategic collaboration to develop an mRNA vaccine against COVID-19.

11. While traditional vaccines work by introducing a weakened or inactivated form of a virus or bacterium into the body to trigger an immune response, mRNA vaccines work differently, as follows:

(a) mRNA is encapsulated into a lipid nanoparticle ("**LNPs**"), which protects the mRNA and helps it cross the cell membrane;

(b) once the LNP is inside the cell, the mRNA is released and instructs the cell to produce a harmless piece of the virus – usually a specific protein;

(c) the immune system then recognizes this protein as foreign and mounts an immune response, preparing the body to fight the virus if encountered in the future; and

(d) after the protein is produced, the mRNA is naturally broken down into harmless fragments within a few days.

12. On September 16, 2020, the Minister of Health for Canada approved an *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* (the "**ISAD IO**") to expedite the authorization process for potential COVID-19 vaccines.

13. The ISAD IO permitted manufacturers to present vaccine-related regulatory submissions to Health Canada on a rolling basis (i.e., data could be presented as it was collected throughout the various phases of the clinical trials), permitting Health Canada to review information as it became available.

14. Authorization required sufficient evidence to support the conclusion that the benefits associated with the vaccine outweighed the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health needs related to the COVID-19 pandemic.

15. An application for interim authorization was required to include, among other things, the known information in relation to the quality, safety, and effectiveness of the relevant vaccine as well as a "statement of all of the representations to be made for the promotion of the drug respecting, (i) the recommended route of administration of a drug, (ii) the proposed dosage of the drug, (iii) the drug's indications, (iv) the contra-indications and side effects of the drug."

16. At no time did the ISAD IO alter or diminish existing regulatory requirements for the approval of vaccines. Rather, it was Health Canada's adaptation of its normal review process to advance vaccine authorization by permitting for a rolling submission of application materials across the review period.

17. During the development of the Pfizer-BioNTech COVID-19 Vaccine, and with the knowledge and approval of regulators, the Pfizer-BioNTech COVID-19 Vaccine manufacturing process underwent adjustments over time including for scalability in preparation for high volume manufacture.

18. Adjustments to the manufacturing process over time, including for scalability, are commonplace for new drug and vaccine products. There was nothing exceptional or improper about the Pfizer-BioNTech COVID-19 Vaccine manufacturing process adjustments over time.

19. Two active substance processes were used during the development of the Pfizer-BioNTech COVID-19 Vaccine: Process 1 and Process 2.

20. The two processes were assessed by comparability studies and characterisation testing to confirm that the active substances were comparable across Process 1 and Process 2. Testing was conducted for all manufacturing sites and submitted for review and approval to regulatory authorities.

21. Contrary to the allegations in the Fresh as Amended Statement of Claim, batches of the the Pfizer-BioNTech COVID-19 Vaccine manufactured under Process 2 were also the subject of clinical studies.

22. The Pfizer-BioNTech COVID-19 Vaccine met the requirements of the ISAD IO. On December 9, 2020, Health Canada authorized the use of the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years or older (the "**Interim Authorization**").

23. As part of the Interim Authorization, Health Canada imposed various terms and conditions with respect to, among other things, the submission to Health Canada of clinical data, safety, labelling, and other elements relating to the Pfizer-BioNTech COVID-19 Vaccine. The defendants complied with the terms and conditions.

24. On May 3, 2021, Health Canada issued *IO No. 2 Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19* ("**IO No. 2**") to facilitate clinical trials for potential COVID-19 drugs and medical devices, while upholding patient safety requirements and requiring the validity of trial data.

25. IO No. 2 was eventually replaced with Health Canada's *Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations: SOR/2022-18*, which came into effect on February 27, 2022.

26. On September 16, 2021, the Pfizer-BioNTech COVID-19 Vaccine was transitioned from being authorized under the ISAD IO to being authorized under Part C, Division 8 of the *Food and Drug Regulations*. Health Canada issued a Notice of Compliance ("**NOC**") authorizing the vaccine for use to prevent COVID-19 in individuals 12 years of age and older.

27. Since receiving Interim Authorization under the ISAD IO on December 9, 2020, the Pfizer-BioNTech COVID-19 Vaccine has continuously been authorized for distribution in Canada.

iv. The Product Monograph

28. At all relevant times, all material information relating to the side effects of the Pfizer-BioNTech COVID-19 Vaccine was reported and disclosed to Health Canada in accordance with the applicable regulatory obligations.

29. Warnings were provided regarding known adverse effects and side effects relating to the Pfizer-BioNTech COVID-19 Vaccine in the publicly available product monograph (the "**Product Monograph**").

30. A product monograph is a factual, scientific document, devoid of promotional material, which describes the properties, claims, indications, and conditions of use for a specific drug product, as well as any other information that may be required for optimal, safe, and effective use.

31. The Product Monograph includes, among other things:

(a) dosage and administration information for physicians, pharmacists and/or other health care professionals (collectively, "**Health Care Professionals**");

(b) information regarding the Pfizer-BioNTech COVID-19 Vaccine's characteristics and the clinical trials conducted to assess the efficacy of the Pfizer-BioNTech COVID-19 Vaccine; and

(c) safety information regarding the Pfizer-BioNTech COVID-19 Vaccine for consumers, including disclosure reported side effects and any risks of adverse effects arising from the use of the vaccine.

32. Health Canada specifically reviewed and approved the Product Monograph as part of the regulatory approval process for the Pfizer-BioNTech COVID-19 Vaccine.

33. The Product Monograph was subsequently published on Health Canada's website. It has been revised from time-to-time to include additional information as it became available.

34. In addition to being posted on Health Canada's website, at all relevant times, the Product Monograph was also:

(a) available to Health Care Professionals on CVDVaccine.ca and COMIRNATY.ca; and

(b) accessible by scanning the QR code on the carton label for each dose of the Pfizer-BioNTech COVID-19 Vaccine.

35. Contrary to the allegations in the Fresh as Amended Statement of Claim, including paragraphs 98-99, and 101, as early as June 30, 2021, about two months before Sean Hartman received a dose of the Pfizer-BioNTech COVID-19 Vaccine, the Product Monograph stated, under the heading Warnings and Precautions:

> Very rare cases of myocarditis and/or pericarditis following vaccination with Pfizer-BioNTech COVID-19 Vaccine have been reported during post-authorization use. These cases occurred more commonly after the second dose and in adolescents and young adults. Typically, the onset of symptoms has been within a few days following receipt of the Pfizer-BioNTech COVID-19 Vaccine. Available short-term follow-up data suggest that the symptoms resolve in most individuals, but information on long-term sequelae is lacking. The decision to administer the Pfizer-BioNTech COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances.
>
> Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with a COVID-19 vaccine. This could allow for early diagnosis and treatment. Cardiology consultation for management and follow up should be considered.

36. The very rare cases of myocarditis and/or pericarditis following vaccination with the Pfizer-BioNTech COVID-19 Vaccine are not caused by any negligent design, manufacture or other tortious act of the defendants.

37. In any event, a COVID-19 infection poses higher risks for cardiovascular complications (including myocarditis and and/or pericarditis) than the transient myocarditis and/or pericarditis risk, if any, caused by the Pfizer-BioNTech COVID-19 Vaccine.

38. Notwithstanding the very rare cases of myocarditis and/or pericarditis reported during post-authorization use, Health Canada continued to find that benefits of the Pfizer-BioNTech COVID-19 Vaccine outweighed the risks.

39. The Pfizer-BioNTech COVID-19 Vaccine remained at all relevant times authorized for use by Health Canada for individuals 16 years or older, and individuals 12 years of age and older since December 9, 2020, and September 16, 2021, respectively.

v. Additional Post-Authorization Reporting and Publicly Available Information

40. Following the authorization of the Pfizer-BioNTech COVID-19 Vaccine, Pfizer provided ongoing disclosure and pharmacovigilance reporting to Health Canada regarding the efficacy and risks associated with the Pfizer-BioNTech COVID-19 Vaccine.

41. Safety information and disclosure was made available to Health Care Professionals and the public in hard copy and downloadable electronic formats, as a separate "Patient Information" leaflet directed towards individuals receiving a dose of the Pfizer-BioNTech COVID-19 Vaccine.

42. Health Canada published or made publicly available the various materials, each of which provided public disclosure regarding the uses and risks of the Pfizer-BioNTech COVID-19 Vaccine, including in:

(a) health product risk communications, posted online each time the Pfizer-BioNTech COVID-19 Vaccine was authorized for use with a new consumer population, or a new formulation was authorized;

(b) adverse event reports, containing reports of suspected adverse events and other incidents submitted by members of the public (without any vetting by Health Canada) to Health Canada's Vigilance Program; and

(c) a website listing suspected adverse events following vaccination.

C. DEFENCES

43. BioNTech expressly denies that it has been negligent or has breached any duty, either statutory or at common law, as alleged in the Fresh as Amended Statement of Claim or at all.

44. BioNTech is unaware whether Sean Hartman received any dose(s) of the Pfizer-BioNTech COVID-19 Vaccine as alleged in paragraph 75 of the Fresh as Amended Statement of Claim.

45. If Sean Hartman received a dose of the Pfizer-BioNTech COVID-19 Vaccine as alleged, BioNTech denies that Sean Hartman suffered any injuries or died as a result of taking the Pfizer-BioNTech COVID-19 Vaccine, as alleged in the Fresh as Amended Statement of Claim or at all.

i. No Common Design

46. In response to the allegations of "common design" pleaded at paragraphs 37-38 of the Fresh as Amended Statement of Claim:

(a) there is no cause of action of "common design";

(b) BioNTech, Pfizer Inc. and Pfizer Canada ULC are each separate corporate personalities;

(c) Pfizer exerts no strategic or financial control over BioNTech;

(d) BioNTech exerts no strategic or financial control over Pfizer; and

(e) the plaintiff has failed to plead the necessary elements to invoke the common design doctrine, including because there is nothing unlawful about developing and manufacturing a pharmaceutical product under rigorous regulatory oversight.

ii. No Negligence

47. BioNTech denies that it was negligent in any manner and further denies that it breached any duty of care, including any duties of care informed by statutory or regulatory law, alleged to be owed to Sean Hartman.

48. BioNTech specifically denies the allegations of negligence, breach of the duty to warn, negligent misrepresentation contained in paragraphs 80-103 of the Fresh as Amended Statement of Claim, or at all.

49. BioNTech specifically denies breach of any duty or standard of care, either statutory or at common law, in relation to the development, design, formulation, research, testing, manufacture, packaging, marketing, distribution, sale, or reporting in respect of the Pfizer-BioNTech COVID-19 Vaccine as alleged in the Fresh as Amended Statement of Claim, or at all.

50. At all relevant times, the defendants complied with the applicable legislative and regulatory framework, which compliance principally establishes that the applicable standard of care was met.

a. No Negligent Design

51. BioNTech denies the allegations of negligent design as described at paragraphs 87-90 of the Fresh as Amended Statement of Claim, or at all.

52. The Pfizer-BioNTech COVID-19 Vaccine was designed with appropriate care and was appropriate for its intended purpose. The benefits of the Pfizer-BioNTech COVID-19 Vaccine outweighed the risks, as determined and confirmed by Health Canada.

53. The Pfizer-BioNTech COVID-19 Vaccine, and the design of the same, do not create a substantial likelihood of harm. Furthermore, there is no alternative design that is safer and economically feasible to manufacture (and the plaintiff has not properly pleaded an alternative design that is safer and economically feasible to manufacture).

54. At all material times, the design of the Pfizer-BioNTech COVID-19 Vaccine complied with all applicable common law, regulatory and industry standards.

b. No Negligent Manufacture

55. BioNTech denies the allegations of negligent manufacture as described at paragraphs 91-96 of the Fresh as Amended Statement of Claim, or at all.

56. BioNTech met the applicable standard of care in relation to the manufacture of the Pfizer-BioNTech COVID-19 Vaccine at all material times.

57. The Pfizer-BioNTech COVID-19 Vaccine was manufactured in accordance with its specifications as well as applicable regulatory and industry standards, including international standards of Good Manufacturing Practice. Manufacturing sites were subject to regulatory approval, and were inspected on a regular basis.

c. No Negligent Misrepresentation or Breach of the Duty to Warn

58. BioNTech denies the allegations of negligent misrepresentations as described at paragraphs 82-86 and paragraph 105(a) of the Fresh as Amended Statement of Claim, or at all.

59. In response to the allegations at paragraphs 59-65, Pfizer issued various press releases in respect of the Pfizer-BioNTech COVID-19. The content of the press releases was accurate at the time they were released and remains accurate today.

60. Contrary to the allegations at paragraph 59-65, the press releases reporting on clinical trial data included clinical trial data regarding batches of the Pfizer-BioNTech COVID-19 Vaccine manufactured under Process 2, which batches are biologically, chemically, and physically comparable to batches manufactured under Process 1 in any event.

61. BioNTech denies that it breached any duty to warn as described at paragraphs 97-103 of the Fresh as Amended Statement of Claim, or at all.

62. BioNTech denies that the risks and outcomes of the Pfizer-BioNTech COVID-19 Vaccine were concealed from the public, Health Care Professionals, and regulatory authorities including Health Canada.

63. BioNTech denies all of the allegations of wilful disregard for public safety, including ignoring or downplaying risks of adverse events arising from use of the Pfizer-BioNTech COVID-19 Vaccine.

64. BioNTech denies that the warnings provided for the Pfizer-BioNTech COVID 19 Vaccine were inadequate, and denies that the warnings failed to disclose the risk of, among other things, myocarditis.

65. At all relevant times, clear and adequate information and warnings about the known and reasonably foreseeable risks inherent in the use of the Pfizer-BioNTech COVID-19 Vaccine were provided, including in the Product Monograph.

66. At all relevant times, patients were expressly warned about the limits of the information contained in the Patient Information leaflet and were directed to consult with their Health Care Professionals to learn more about the Pfizer-BioNTech COVID-19 Vaccine.

67. At all relevant times, the Pfizer-BioNTech COVID-19 Vaccine was distributed with proper warnings of all known or reasonably knowable or foreseeable risks associated with the use of the vaccine at the time of authorization and distribution, including with information regarding contraindications and potential adverse effects, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

68. BioNTech denies that the results of the clinical and safety trials were disregarded and misrepresented knowingly or recklessly, as alleged in the Fresh as Amended Statement of Claim or at all.

69. BioNTech further denies that any allegedly different or additional warning would have altered the clinical recommendation or the decision to vaccinate in Sean Hartman’s specific circumstances.

70. In the alternative, if any representation by BioNTech is found to be inaccurate in any respect (which is denied), BioNTech pleads that any such inaccuracy was neither material nor reasonably relied upon by Sean Hartman or his guardians, including the Plaintiff, or any healthcare professional allegedly involved in administering the Pfizer-BioNTech COVID-19 Vaccine.

iii. Adequate Warnings to Learned Intermediaries

71. BioNTech does not market or sell the Pfizer-BioNTech COVID-19 Vaccine to patients directly. Rather, it relies on physicians, pharmacists, and other Health Care Professionals involved to dispense and administer the Pfizer-BioNTech COVID-19 Vaccine.

72. Health Care Professionals apply, as appropriate, their clinical knowledge and expertise in weighing the risks and benefits associated with the use or non-use of the Pfizer-BioNTech COVID-19 Vaccine for each patient, including by explaining the risks and benefits associated with the use or non-use of the Pfizer-BioNTech COVID-19 Vaccine in each case, and in obtaining each patient's informed consent.

73. BioNTech pleads and relies on the learned intermediary defence. BioNTech's obligation to provide adequate warnings to the public was discharged by the adequate warnings provided to Health Canada and Health Care Professionals.

iv. No Breach of Statutory Duties

74. BioNTech denies any breach of statutory duties, as described at paragraphs 104-108 of the Fresh as Amended Statement of Claim, or at all.

75. At all relevant times, the defendants complied with the applicable legislative and regulatory framework, which compliance principally establishes that the applicable standard of care was met.

v. No Wrongful Death and No Recovery Under the FLA

76. BioNTech denies the allegations of wrongful death as described at paragraphs 109-119 of the Fresh as Amended Statement of Claim, or at all.

77. Wrongful death is not an independent common law cause of action in Ontario; any recovery by family members in respect of a fatality is governed exclusively by *Family Law Act*, RSO 1990, c F.3 ("*FLA*"). The Plaintiff has not pleaded or established any actionable tort by BioNTech that could ground derivative recovery by a family member.

78. As there has been no tortious non-disclosure, negligence, or breach of duty, either statutory or at common law, on the part of BioNTech, there is therefore no injury, loss, or damage suffered for which the requisite causal nexus can be established.

79. BioNTech pleads that no recovery is available for the Plaintiff under the *FLA* or otherwise.

vi. No Provable Damages

80. If Sean Hartman received a dose of the Pfizer-BioNTech COVID-19 Vaccine as alleged, BioNTech denies that Sean Hartman died or suffered any compensable injury as a result of the Pfizer-BioNTech COVID-19 Vaccine.

81. BioNTech pleads that there is no established causal nexus between the administration of the Pfizer-BioNTech COVID-19 Vaccine and the death and injuries of Sean Hartman alleged in the Fresh as Amended Statement of Claim, or at all.

82. BioNTech pleads that the Plaintiff's and Sean Hartman's injuries, losses, damages, or expenses resulted from a natural cause, pre-existing medical or health condition, and/or were idiosyncratic and not foreseeable.

83. BioNTech therefore denies the claims of the Plaintiff for general or special damages and loss as alleged or otherwise, including but not limited to:

(a) loss of care, guidance and companionship;

(b) emotional shock and mental anguish, resulting in severe depression and post-traumatic stress disorder;

(c) pecuniary losses; and

(d) any other damages or loss, as alleged in the Fresh as Amended Statement of Claim or otherwise.

84. The damages claimed are indirect, exaggerated, speculative, remote, and not causally connected to any act, omission, or negligence on the part of BioNTech, and therefore not recoverable from BioNTech at law.

85. In any event, the Plaintiff may claim compensation from the Vaccine Injury Support Program ("**VISP**"), a no-fault compensation scheme, for any alleged injuries reported to a Health Care Professional in connection with receiving a vaccine.

86. The VISP provides financial support to eligible claimants regardless of the responsibility or possible fault of vaccine manufacturers.

vii. No Basis for Punitive, Aggravated, Special, or Exemplary Damages

87. BioNTech did not commit any act or make any omission that was malicious, willful, wanton, reckless, grossly negligent, or intentional, either as alleged or at all.

88. BioNTech denies engaging in any conduct that would justify an award of punitive, aggravated, special, and/or exemplary damages.

89. BioNTech has acted lawfully and appropriately at all times, and the Plaintiff's allegations in support of the claim for are unfounded and tantamount to an allegation of fraud. As such, the plaintiff should be required to pay an award of costs to BioNTech on a full indemnity basis.

viii. The Plaintiff's Claim is Statute-Barred

90. The Plaintiff's claim is statute-barred, in whole or in part, by the operation of the *Limitations Act, 2002*. The Plaintiff was aware, or ought to have been aware, of the material facts upon which a plausible inference of liability (which liability is denied) could have been drawn more than two years before he commenced this proceeding.

91. BioNTech pleads and relies upon:

(a) the *Family Law Act*, RSO 1990, c F.3 (as may be amended) and any regulations thereunder;

(b) the *Food and Drugs Act*, RSC, 1985, c F-27, (as may be amended) and any regulations thereunder;

(c) the *Negligence Act*, RSO 1990, c N.1 (as may be amended) and any regulations thereunder; and

(d) the *Limitations Act, 2002,* SO 2002, c 24, Sched B (as may be amended) and any regulations thereunder

92. BioNTech requests that this action be dismissed against it, with costs.

December 5, 2025

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Daniel Hartman
Plaintiff

-and-

Pfizer Inc. et al.
Defendants

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PROCEEDING COMMENCED AT
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STATEMENT OF DEFENCE OF BIONTECH MANUFACTURING GMBH

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